DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JUL 27 2015

Val Med Corpration
% Mr. Howard M. Holstein, Esq.
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Columbia Square
Washington, D.C. 20004

Re: K010754
Trade/Device Name: Val Med Corporation Nurse's Assistant O.R. Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, FET, FSY, HET, HIF, GEI and LMC
Dated (Date on orig SE ltr): July 5, 2001
Received (Date on orig SE ltr): July 5, 2001

Dear Mr. Holstein,

This letter corrects our substantially equivalent letter of August 15, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K010754

Device Name: **Val Med Corp. Nurse's Assistant O.R. Control System**

Indications for Use:

The Nurse's Assistant is intended to be used to turn on and off and adjust certain settings of endoscopic and surgical cameras, surgical lamps, and operating room ("O.R.") lights, and to operate VCRs, monitors, video printers, radios, and CD players.

The Val Med Nurse's Assistant is indicated for use in general, cardiovascular, ENT, gastroenterology, urology, plastic, obstetrics, gynecology, and orthopedic surgery, and general thorascoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy. A few examples of the more common surgical procedures where this system could be used are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anteriorspinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated, examination of the evacuated cardiac chamber during performance of valve replacement, arthroscopic meniscus repair, anterior cruciate ligament repair and associated procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

Mark N Milhern
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Optional Format 1-2-96)

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510(k) Number K010754

K010754

AUG 1 5 2001

510(k) SUMMARY

Val Med's Nurse's Assistant O.R. Control System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Val Med Corp.
4800 NW Saltzman Road
Portland, Oregon 97229
Telephone: (503) 614-1106
Facsimile: (503) 614-1109

Contact Person: Darko Spoljaric
Vice President

Date Prepared: March 13, 2001

Name of Device and Name/Address of Sponsor

Val Med Corp.
4800 NW Saltzman Road
Portland, Oregon 97229
Telephone: (503) 614-1106
Facsimile: (503) 614-1109

Common or Usual Name

Surgical Control Center

Classification Name

Accessory to a Ceiling Mounted Surgical Lamp
Accessory to a Medical Image Storage Device
Accessory to a Laparoscope, General & Plastic Surgery

Predicate Devices

Computer Motion's Hermes Operating Room Control Center
Olympus EndoAlpha
Karl Storz KSEA SCB-RUI
Hill-Rom, Inc.'s BrightStar©
American Sterilizer Co.'s Quantum©, SQ24

Getinge/Castle, Inc. OptiView©, 500 series

Intended Use / Indications for Use

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Performance Data

The Nurse's Assistant's control unit meets EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety 4: Collateral Standard: Programmable Electrical Medical Systems.

The Nurse's Assistant's power supply meets UL 2601-1 "U.L. Standard for Safety for Medical Electrical Equipment – General Requirements for Safety".

The Nurse's Assistant's controlling software meets ANSI standard 1375-221.

Technological Characteristics

The Val Med's Nurse's Assistant is a computer with a monitor and touch screen that a nurse uses in the operating room to activate and control the following equipment: (1) surgical cameras, including an endoscopic camera;

(2) room or surgeons'/nurses' lounge cameras ("operating room cameras");[1] (3) surgical lights; (4) room lights; (5) a VCR;[2] (6) a video printer; (7) video monitor(s);[3] (8) a radio; and (9) a CD player.[4] Val Med's Nurse's Assistant controls one or more electrical dimmer switches, which in turn control the surgical lights.

Substantial Equivalence

The Nurse's Assistant has the same intended use and similar indications for use and technological characteristics as its predicate, Computer Motion's Hermes Operating Room Control Center, the Olympus EndoAlpha, and the Storz KSEA SCB-RUI. In addition, the surgical lamp that is used with the Nurse's Assistant is substantially equivalent to Hill-Rom, Inc.'s BrightStar©, American Sterilizer Co.'s Quantum©, SQ240, and Getinge/Castle, Inc. OptiView©, 500 series. Therefore, the Nurse's Assistant is substantially equivalent to its predicate devices.

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1 We believe that these surgical cameras are Class I exempt devices, under 21 C.F.R. § 878.4160.

2 We believe that the VCR is a medical image storing device under 21 C.F.R. § 892.2010(a), which is, therefore, a Class I exempt storage device. Alternatively, it is not a medical device, subject to FDA regulation.

3 We believe that these monitors are accessories to medical image communications devices. As such, theses monitors are Class I exempt from 510(k) requirements under 21 C.F.R. § 892.2020(a), which states that a "medical image communications device" provides "electronic transfer of medical images between medical devices."

4 We have not been able to identify any device classification regulations that encompass operating room lights, operating room cameras, speakerphones, radios, and CD players nor have we identified any cleared devices like these products. For this reason, we believe that these products are not medical devices and the company will not make medical claims related to these components.